



CASE 1908

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

SHI, ET AL.

S.N. 09/817,419

FILED: 26 MARCH 2001

FOR: CEREAL GRAINS WITH HIGH TOTAL
DIETARY FIBER AND/OR RESISTANT
STARCH CONTENT AND
PREPARATION THEREOF

Group Art Unit: 1761

Examiner: TRAN LIEN, THUY

Commissioner of Patents and Trademarks

Washington, D.C. 20231

APPEAL BRIEF

Sir:

Applicants appeal the Office Action dated 25 March 2003 in the above-identified application.

I. Brief Filing Deadline Statement

This is an appeal from the Office Action dated 25 March 2003. A Notice of Appeal was filed on 25 June, 2003, making Appellant's Brief due on 25 August, 2003, extended one month by petition herewith to 25 September, 2003. This Brief is being filed in triplicate as required under 37 C.F.R. 1.192(a).

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II. Fee Statement

Payment of the Appeal Brief Fee is authorized in an accompanying fee payment document, as required under 37 C.F.R. 1.17(f).

III. Real Party in Interest

National Starch and Chemical Investment Holding Corporation, the assignee, is the real party in interest.

IV. Related Appeals and Interferences

There is currently no related appeal or interference pending in the United States Patent and Trademark Office.

V. Status of Claims

Claims 1-21 were originally filed in an application dated 26 March, 2001. In the first Office Action dated 24 April, 2002, claims 1-20 were rejected under 35 U.S.C. §112 for indefiniteness, claims 1, 2, 4, 5, 8, 10, and 11-15 under 35 U.S.C. §102(b) as being anticipated by Whitney, et al. (US 5,972,413), and claims 3, 6-7, 9, and 16-21 under 35 U.S.C. §103(a) as being unpatentable over Whitney, et al. (US 5,972,413) in view of Ferguson, et al. (US 5,300,145). Claims 1, 3, 4, 6, 9, 13-14, 16-18 and 20-21 were amended, claim 2 was canceled and claims 22-41 were added in the Amendment filed 19 September 2002.

In the Final Action dated 06 December, 2003, claims 1, 4, 5, 8, 10, and 11-15 were rejected under 35 U.S.C. §102(b) as being anticipated by Whitney, et al. (US 5,972,413), and claims 3, 6-7, 9, and 16-41 under 35 U.S.C. §103(a) as being unpatentable over Whitney, et al. (US 5,972,413) in view of Ferguson, et al. (US 5,300,145). A telephonic interview was conducted between the Examiner and the Attorney of Record without agreement being reached.

A Request for Continued Examination was filed on 5 March, 2003, along with a Preliminary Amendment and a Declaration under Rule 132 (37 C.F.R. §1.132). Claim 1 was amended at such time.

In the Office Action dated 25 March, 2003, claims 1, 2 [sic], 4, 5, 8, 10, and 11-15 were rejected under 35 U.S.C. §102(b) as being anticipated by Whitney, et al. (US 5,972,413), and claims 3, 6-7, 9, and 16-41 under 35 U.S.C. §103(a) as being

unpatentable over Whitney, et al. (US 5,972,413) in view of Fergason, et al. (US 5,300,145). No amendments were made to the claims in response thereto. A Notice of Appeal was filed in reply.

Claims 1 and 3-41 are currently pending and are under appeal. The claims as currently pending are in Appendix A.

VI. Status of Amendments

All amendments were considered.

VII. Summary of Invention

Dietary fiber and resistant starch content have both been linked to numerous health benefits such that many countries have recommended the increased consumption of such foods as a part of their dietary guidelines. These health benefits include good colonic health and more consistent glycemic response.

This application pertains to novel cereal grains, which have increased dietary fiber and/or resistant starch content and the process of preparing such cereal grains. The grains are produced by heating at various combinations of temperature and moisture, which do not destroy the granular structure or birefringence of the starch granule. Increasing the dietary fiber and/or resistant starch content of the grain allows whole grain foods to be prepared with important nutritional benefits.

It is important to understand that the granular structure must remain to achieve the benefits of the claimed invention. The amylose and amylopectin molecules of starch are arranged to form a starch granule. This granule is insoluble in water. The granule does contain some residual amounts of water which interact with the hydroxyl groups present in the amylose and amylopectin molecules to produce hydrogen bonding between the individual glucose molecules. Starch granules are partially crystalline. When the water temperature is raised, diffusion of water into the starch granule begins and the granule starts to swell, the areas within the granule that are crystalline change and the loss of birefringence occurs, which is seen using polarized light on a microscope. Shortly thereafter, with continued heat, the granule swells further until a viscosity rise occurs followed by the granule breaking apart to

release the starch polymers into the water. This process is generally termed gelatinization and is irreversible.

Each starch has its own gelatinization curve, such that a particular combination of temperature, moisture and time which is sufficient to completely gelatinize one starch may not be sufficient to completely gelatinize another. Thus, the claims of the present invention are limited to a combination of conditions such that the starch does not have its granular structure and birefringence completely destroyed. This is necessary to result in the increased level of total dietary fiber.

VIII. References

The outstanding rejections are based on the following references.

| | | |
|------------------|--------------|------------|
| Whitney, et al. | US 5,972,413 | "Whitney" |
| Ferguson, et al. | US 5,300,145 | "Ferguson" |

IX. Issues

- A. Are claims 1, 4, 5, 8, 10, and 11-15 patentable over Whitney?
- B. Are claims 3, 6-7, 9, and 16-41 patentable over Whitney in view of Ferguson?

X. Grouping of Claims

Appellants consider each claim under appeal herein to be separately patentable.

Claim 1 is an independent claim directed to a method for preparing a grain containing starch with increased total dietary fiber content comprising heating a base grain having a total moisture content of from about 20% to about 45% by weight based on the dry weight of the grain, at a temperature of from about 90°C to about 130°C for a period of about 0.5 to 24 hours, under a combination of moisture and temperature conditions such that the starch does not have its granular structure and birefringence completely destroyed and to provide a heat-treated-grain having an increase in total dietary fiber content of at least 10%.

Claim 3 is dependent upon claim 1 and limits the base grain to that which contains a starch having at least 40% by weight amylose content.

Claim 4 is dependent upon claim 1 and limits the temperature to between about 90 °C to about 125 °C.

Claim 5 is dependent upon claim 1 and limits the base grain to corn.

Claim 6 is dependent upon claim 1 and limits the base grain to that which contains a granular starch that has at least 65% by weight amylose content.

Claim 7 is dependent upon claim 1 and limits the base grain to one which is degerminated.

Claim 8 is dependent upon claim 1, and limits the total moisture content of the base grain to from about 20% to about 45% and the temperature to between about 90 °C to about 125 °C.

Claim 9 is dependent upon claim 1 and limits the base grain to one which is obtained from a plant source having an amylose extender genotype, the starch comprising less than 10% amylopectin as determined by butanol fractionation/exclusion chromatography measurement.

Claim 10 is dependent upon claim 9 and limits the base grain to one with a total moisture content of from about 20% to about 35% and the heating to a temperature of from about 90 to 120°C.

Claim 11 is directed to the grain made by the method of claim 1.

Claim 12 is dependent upon claim 11 and limits the grain to that having an increase in TDF content of greater than 30%.

Claim 13 is dependent upon claim 11 and limits the grain to that having a higher onset temperature than a corresponding untreated grain.

Claim 14 is dependent upon claim 13 and limits the grain to having a higher delta H than a corresponding untreated grain.

Claim 15 pertains to the grain made by the method of claim 3 having a higher TDF and RS than a corresponding untreated grain.

Claim 16 is dependent upon claim 11 and limits the grain to that in which the amylose content is between about 50 to about 69% by weight of the starch and having a TDF of at least than 45%.

Claim 17 is dependent upon claim 11 and limits the grain to that in which the amylose content of the starch is between about 70 and about 89% and having a TDF content of at least 58%.

Claim 18 is dependent upon claim 11 and limits the grain to that in which the amylose content of the starch is greater than 90% and having a TDF content of at least 75%.

Claim 19 pertains to the starch isolated from the heat-treated grain of claim 11.

Claim 20 pertains to a food product containing a grain prepared by the method of claim 1.

Claim 21 is dependent upon claim 20 and limits the food to that selected from the group consisting of cereal, bread, crackers, cookies, cakes, pasta, beverages, fried and coated foods, snacks, dairy products, and cheeses.

Claim 22 is independent and is directed to a method for preparing a grain containing starch with increased total dietary fiber content comprising heating a grain containing starch having at least about 40% by weight amylose, said grain having a total moisture content of from about 8% to about 85% by weight based on the dry weight of the grain, at a temperature of from about 65°C to about 150°C, under a combination of moisture and temperature conditions to provide a heat-treated-grain having an increase in total dietary fiber content ("TDF") of at least 10%.

Claim 23 is dependent upon claim 22 and is limited in that the starch does not have its granular structure completely destroyed.

Claim 24 is dependent upon claim 22 and is limited such that the total moisture content of the base grain is from about 24% to about 55% and the temperature is between about 90 °C to about 125 °C.

Claim 25 is dependent upon claim 22 and is limited such that the base grain is corn.

Claim 26 is dependent upon claim 22 and is limited such that the base grain contains a granular starch that has at least 65% by weight amylose content.

Claim 27 is dependent upon claim 22 and is limited such that the base grain is degerminated.

Claim 28 is dependent upon claim 22 and is limited such that the total moisture content of the base grain is from about 20% to about 45% and the temperature is between about 90 °C to about 125 °C.

Claim 29 is dependent upon claim 22 and is limited such that the base grain is obtained from a plant source having an amylose extender genotype, the starch

comprising less than 10% amylopectin as determined by butanol fractionation/exclusion chromatography measurement.

Claim 30 is dependent upon claim 29 and is limited such that the base grain has a total moisture content of from about 20% to about 35% and the heating is at a temperature of from about 90 to 120°C.

Claim 31 is directed to a grain made by the method of claim 22.

Claim 32 is dependent upon claim 31 and is limited such that the grain has an increase in TDF content of greater than 30%.

Claim 33 is dependent upon claim 31 and is limited in that the grain has a higher onset temperature than a corresponding untreated grain.

Claim 34 is dependent upon claim 33 and is limited to a grain having a higher delta H than a corresponding untreated grain.

Claim 35 is directed to a grain made by the method of claim 22 having a higher TDF and RS than a corresponding untreated grain.

Claim 36 is dependent upon claim 31 and is limited to a grain in which the amylose content is between about 50 to about 69% by weight of the starch and having a TDF of at least 45%.

Claim 37 is dependent upon claim 31 and is limited to grain in which the amylose content of the starch is between about 70 and about 89% and having a TDF content of at least 58%.

Claim 38 is dependent upon claim 31 and is limited to a grain in which the amylose content of the starch is greater than 90% and having a TDF content of at least 75%.

Claim 39 is directed to a starch isolated from the heat-treated grain of claim 31.

Claim 40 is directed to a food product containing a grain prepared by the method of claim 22.

Claim 41 is dependent upon claim 40 and is limited to a food selected from the group consisting of cereal, bread, crackers, cookies, cakes, pasta, beverages, fried and coated foods, snacks, dairy products, and cheeses.

XI. Argument

A. Are claims 1, 4, 5, 8, 10, and 11-15 patentable over Whitney?

The answer is clearly yes, the claims are patentable over Whitney. These claims are directed to a method for preparing a grain containing starch with increased total dietary fiber (TDF) content comprising heating the grain under certain conditions, such that the starch does not have its granular structure and birefringence completely destroyed, to provide an increase in total dietary fiber content of at least 10%.

Whitney states that his process has the advantageous property of gelatinization (see col. 2, lines 28-30). In contrast, claim 1 of the present invention is limited to starch in which the granules in the heat-treated grain are not completely destroyed and thus are not fully gelatinized. The Examiner found the argument above unpersuasive as Whitney “does not in any way indicate fully gelatinization; there is varying degree of gelatinization.” Applicants respectfully traverse.

To determine the meaning of cooked or gelatinization, one skilled in the art would look at the entire disclosure of Whitney. The invention of Whitney is “a process for cooking cereal grains.” See the Technical Field. Whitney continues by explaining that “when cooked in this way” the grains are “well suited to further processing, particularly shredding.” One skilled in the art would understand this to mean that the starch in the grain must be gelatinized (fully cooked) as supported at column 2, line 64. If the starch is not fully gelatinized, the grain will not shred properly and will have undesirable eating properties, texture and appearance. This is further supported at column 2, lines 28-32, which states that the cooked grain has the advantageous properties of gelatinization of the starch and the ... berries are both evenly and completely cooked.” Further, the only example in Whitney teaches fully cooking the wheat berries. Although Whitney does state “substantially fully cooked” in col. 3, line 2, as stated by the Examiner, this has to be read in context with the entire specification which clearly indicates that the intent of the invention is to fully cook the berries and thus fully gelatinize the starch. Such intent is further evident from the background of the invention which states that the prior art method of batch cooking has the major disadvantage of inconsistency of cook.

In contrast, the present invention is directed to grain in which the granular structure is not completely destroyed. The Examiner has alleged that it is not clear what range of gelatinization the claimed language of “not completely destroyed” covers. Once again, the language must be read in conjunction with the specification which states at page 9 that to obtain a high level of total dietary fiber and/or resistant starch, the granular structure is not completely destroyed. The specification then expounds upon this concept, stating that the component starch granule may be partially swollen, but its crystallinity is not completely destroyed. The term granular is then defined as a starch that retains at least part of its granular structure, thereby exhibiting some crystallinity, so that the granules are birefringent. Thus, the specification clearly indicates the degree of gelatinization; that is that the starch is not fully gelatinized.

Whitney teaches away from the present invention in that the intent is to fully cook (gelatinize) the starch of the grain which would not result in the increased level of total dietary fiber and/or resistant starch obtained in the present invention. The term “substantially” is intended to mean that while it is the intent that all the grain be gelatinized, one practicing the art would fall within the invention if a few grains are not gelatinized. In contrast, the present invention does not want any of the grains to be fully gelatinized as such grain would not achieve the goal of increased total dietary fiber content.

To further support Applicants claim that the process of Whitney gelatinizes the starch, destroying its granular structure and birefringence, Applicants submitted the declaration of Dr. Yong-Cheng Shi under Rule 132 (37 C.F.R. §1.132). Dr. Shi has extensively worked in the area of starch. Under Dr. Shi’s supervision and guidance, the Example of Whitney was conducted and the starch of the cooked grain was compared to that of the heat-treated grain of the present application. The experiment shows that the starch in Whitney has been completely gelatinized such that it is no longer birefringent. Thus, it is clear that Whitney does not anticipate the present invention.

The Examiner found the declaration to be unpersuasive as “the showing in the micrographs is inconclusive.” Applicants disagree. Figure 1 clearly and conclusively shows that the starch of wheat grains cooked in accordance with the example of

Whitney are gelatinized and no longer birefringent. In contrast, the starch of Figures 2 and 3 are not completely gelatinized and remain granular and birefringent under polarized light. Further support for this interpretation may be found in the DSC data in which no endothermic event is observed for the cooked wheat sample of the Whitney example.

The Examiner further states that “there is no microscopic showing of the heat-treated grains in accordance with the claimed process.” Applicants would like to point out that Figure 3 shows the starch of the heat-treated grains of the present invention and that DSC data has also been presented in the results section of the Declaration.

The Examiner argues that the cooking conditions with respect to the moisture content, temperature and time disclosed in Whitney falls within the range claimed. Applicants disagree in that the cooking conditions of the Whitney example results in a starch that has its granular structure and birefringence totally destroyed as shown in the micrographs and DSC data of the Shi Declaration.

Further, regarding claims 13 and 14, it is clear from the Declaration that the grain of Whitney does not have a higher onset temperature or Delter H than a corresponding untreated grain. This is also indicative that the TDF increase has not been achieved as claimed in claims 12 and 15.

From the evidence, it is clear that it is intended that the Whitney product be gelatinized, that the present claims are not anticipated by Whitney, and that the present invention is patentable.

B. Are claims 3, 6-7, 9, and 16-41 patentable over Whitney in view of Ferguson?

The answer is clearly yes, the claims are patentable over Whitney in view of Ferguson. As detailed above in Argument A, the amended claims differ from those of Whitney, *inter alia*, in that the starch is not gelatinized. As Ferguson does not remedy this deficiency, it is clear that the present claims are patentable over Whitney in view of Ferguson.

Further, regarding the claims which use a high amylose grain as a base, it is clear from the application that the use of high amylose grain is necessary to achieve a high total dietary fiber content as evidenced by Tables 2 and 3 which show the

correlation between high amylose and high TDF content. Neither Whitney nor Fergason teach or suggest that such high TDF content could be achieved. Thus, it is clear that the present claims are patentable over Whitney in view of Fergason.

XII. Conclusions and Relief Requested

For the foregoing reasons, the Honorable Board is respectfully requested to reverse the Examiner's rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) of claims 1 and 2-41 and to direct the Examiner to pass the present application to issue.

Respectfully submitted,

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